



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,028	10/25/2000	Jeffrey Olson	11926-112001	3430

26161 7590 08/23/2004

FISH & RICHARDSON PC  
225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER
----------

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/697,028

Applicant(s)

STANTON, VINCENT P.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicants' response to the office action filed on April 9, 2004 has been entered and considered.
2. The instant application is filed on October 25, 2000, which claims the benefit of a provisional 60/206,613 filed on May 23, 2000.
3. Claims 10-16 are pending.

***Response to arguments***

4. Applicants' response to the office action is fully considered and found persuasive.
5. With reference to the rejection made in the previous office action under 35 USC 103(a) applicants' arguments are fully considered and the rejection is withdrawn in view of the arguments.

***New grounds of rejections***

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 16 recite "amplification primers .... which flank a polymorphic site, one of the two primers including a 5' portion which, when incorporated into an amplification product, will upon further amplification yield products that form a stable-loop structure, the stem of which is perfectly matched and includes the polymorphic site only when the second nucleotide is present at the polymorphic site". It is unclear and indefinite whether the

Art Unit: 1637

amplification primers that flank a polymorphic site do bind or do not bind the polymorphic site, because the first part of the claim 1 and 16 in step (a) disclose that the two primers flank a polymorphic region and do not bind to the polymorphic site, however, in the next part of the step (a) the claims disclose that the stem of the stem-loop is perfectly matched and includes the polymorphic site, contradicting the first part of the claim, which discloses that the primers do not bind to the polymorphic site. The meets and bonds of the claims are not clear.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 10-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Ness et al. (USPN. 6,361,940).

Van Ness et al. teach a method of claim 10, 16, for biasing (presence or absence of a variant) a DNA amplification or haplotyping such that a first nucleic acid having a first nucleic

Art Unit: 1637

acid present at a polymorphic site (mutant or variant nucleotide) to a greater extent than a second nucleic acid molecule having a second, different nucleotide (normal or wild-type nucleotide) at the polymorphic site, (see col. 60, lines 35-67, col. 59, lines 17-67) comprising

(a) contacting a sample DNA with two amplification primers (first and second diagnostic primers) that hybridize to the first (sense) and second (anti-sense) nucleic acid molecules at locations which flank the polymorphic site such that both primers do not hybridize to the polymorphic site (see col. 59, lines 17-67, column 60, lines 35-63, lines 24-47), upon amplification yields extension products that incorporate perfectly matched nucleotides at the polymorphic site, indicating polymorphism and no extension product is formed when the mismatched nucleotide is present at the polymorphic site (see col. 59, lines 17-28)

(b) carrying out an amplification reaction, wherein the first nucleic acid molecule non-wild type nucleotide comprising molecule) is amplified to a greater extent than the second nucleic acid (see col. 60, lines 53-67);

with regard to claim 11 and 12, Van Ness et al. also teach that said DNA is single-stranded or double-stranded (see col. 60, lines 37-38, col. 53, line 1-11);

With regard to claim 13, Van Ness et al. teach that said method comprises detecting plurality of polymorphic sites (see col. 85, lines 51-67);

With regard to claims 14-15, Van Ness et al. teach said method comprises mammalian (human) genomic DNA (see col. 55, lines 20-27, col. 63, line 25-67, col. 64, line 1-17).

Thus the disclosure of Van Ness et al. teach the limitations in the instant claims.

### ***Conclusion***


No claims are allowable.

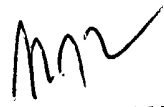
Art Unit: 1637

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782 . The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
August 16, 2004

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
8/16/04